Noninvasive Ventilation Protocol Development

A Scholarly Project

Submitted to the

Faculty of Liberty University

in partial fulfillment of

the requirements for the degree

of Doctor of Nursing Practice

By

Janise P. Tinsman

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Scholarly Project Chair Approval:

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Abstract

Endotracheal intubation results in many serious complications including regurgitation, vocal cord paralysis, and death. Noninvasive ventilation using bi-level positive airway pressure has been shown to provide the necessary support without intubation and is also associated with better outcomes if trialed prior to endotracheal intubation. A noninvasive ventilation protocol was applied in a rural acute care facility. *Results:* The average length of stay for acute respiratory failure decreased from 5.32 to 4.44 days, while intubations fell from 41.9% to zero, and mortality fell from 9.7% to zero during the pilot period. Five cases met criteria for noninvasive ventilation, and three received prompt intervention with lengths of stay of two to four days. One did not have CO2 levels assessed upon admission resulting in delayed noninvasive ventilation, and a twelve-day stay. The fifth refused the therapy and was discharged on hospice.

Keywords: noninvasive ventilation, protocols, endotracheal intubation

Contents

List of Abbreviations

Acute Respiratory Failure (ARF)

Arterial Blood Gases (ABGs)

Bilevel Positive Airway Pressure (BiPAP)

Doctor of Nursing Practice (DNP)

Endotracheal Intubation (ETI)

Institutional Review Board (IRB)

Infectious Disease Society/American Thoracic Society (IDSA/ATS)

Length of Stay (LOS)

Noninvasive Ventilation (NIV)

Partial Pressure of Carbon Dioxide ($PaCO_2$)

Noninvasive Ventilation Protocol Development

Section One

Background

Endotracheal intubation (ETI) is associated with many serious complications including hypoxemia, laryngospasm, airway edema, vocal cord paralysis, regurgitation, cardiovascular collapse, and even cardiac arrest. Patients that present to the hospital in acute respiratory distress or failure have been shown to respond well to noninvasive ventilation (NIV), decreasing the risk of serious trauma from intubation. The Canadian Critical Care Society has developed guidelines for NIV trials prior to invasive ETI. The Infectious Disease Society of America (IDSA) and the American Thoracic Society (ATS) joint guidelines for community acquired pneumonia (CAP) includes a recommendation for NIV protocols. NIV has been proven useful in the management of acute respiratory failure (ARF) associated with chronic obstructive pulmonary disease (COPD) and cardiogenic pulmonary edema (CPE). Development of NIV protocols led to a decrease in the number of ETIs performed, decreasing the trauma associated with this procedure. Use of NIV often resolves the respiratory failure, allows for patient communication and oral intake of nutrition, and supports the patient's respirations rather than taking over the work of breathing.

The facility under study began investigating its respiratory care practices related to a report of higher than expected 30-day pneumonia mortality rates. A gap analysis of the IDSA/ATS guidelines was conducted, with multiple gaps found, including the lack of NIV protocols, which could impact not only pneumonia survival rates, but COPD and CPE outcomes as well. NIV is shown to be effective in ARF with hypoxia, a decreased level of oxygen in the

blood, and hypercapnia, an elevated level of carbon dioxide (CO_2) in the blood. These levels are most accurately measured via arterial blood gas (ABG) measurement.

Historical data was collected on 31 admissions with a diagnosis of ARF between December 27, 2018, and April 12, 2019. Fifteen patients reviewed received ETI with twelve of these occurring in the Emergency Department (ED). The twelve ED intubations recorded two NIV trials prior to intubation, and one patient refusing to keep the NIV mask in place prior to intubation. One patient arrived in the ED already intubated by the Emergency Medical Services team. One patient was intubated in the OR and arrested in the OR. One patient was in the intensive care unit (ICU) and on NIV for two days prior to intubation. One patient who was not hypercapnic in the beginning of their course of treatment placed on NIV for five days with no follow up ABGs and arrested on the fifth day with a $PaCO_2$ of 81.7, with normal values for $PaCO_2$ at 35-45. Four patients with hypercapnia were managed with NIV alone and were not intubated. Establishment of a protocol for monitoring patient response to NIV could prevent the event described above, as periodic monitoring of ABGs would catch the change in $PaCO_2$ to allow intervention before respiratory arrest. Trialing of NIV when possible prior to ETI would reduce the potential damage from the invasive procedure and decrease LOS.

Problem Statement

Lack of an NIV protocol can lead to inconsistent application of this therapy, placing patients at risk for failure to rescue or complications from unnecessary ETI. NIV protocols provide guidelines for consideration of NIV as well as indications for ETI. These guidelines will improve outcomes for patients in ARF.

Purpose of the Project

The purpose of the project is determination of NIV protocols to prompt for rapid application of this therapy in appropriate situations and reduction in the number ETIs for ARF. The NIV protocol is expected to reduce the rate of failure to rescue and ETI in adult ARF patients with improved patient outcomes, including decreased length of stay (LOS) and mortality rates.

Clinical Question

For adult patients presenting to a rural Texas acute care facility with acute respiratory failure (ARF), will a noninvasive ventilation (NIV) protocol decrease the rate of failure to rescue, the number of endotracheal intubations (ETIs), length of stay (LOS), and mortality rates.

Section Two: Literature Review

Search Strategy

A search was conducted using CINAHL, MEDLINE PLUS, the Cochrane Library, and ProQuest Health and Medical Collection databases. Search terms included *noninvasive ventilation* (NIV), *noninvasive positive pressure ventilation* (NPPV), *acute respiratory failure* (ARF), *endotracheal intubation* (ETI), and *protocols*. Twenty-one articles were selected and examined using the Melnyk Levels of Evidence Table. Eighteen studies and articles were found to support the project. Two were studies that were in progress with no results available at the time of the literature search, and three involved equipment or personnel not available in the facility of study.

Critical Appraisal

Six of the studies included were published between 2011 and 2013, with four of these being Level I systematic reviews or practice guidelines. The remaining studies were published

in the past five years. Nine of the studies included in the review are Level I evidence as systematic reviews, meta-analyses, or practice guidelines, seven of which support the use of NIV in reduction of ETI and mortality in ARF. There are two Level II randomized controlled trials that address the issue but are ongoing with no results available. Four Level IV cohort studies are included, two of which indicate ARF patients provided a trial of NIV prior to ETI experience better outcomes than patients intubated without NIV trial. One Level V qualitative analysis is included which also supports NIV in the reduction of ETI. Four Level VI studies are included, one supporting NIV for treatment of ARF in underlying COPD and CPE, one discussing humidification in NIV, one comparing individual physician controlled noninvasive positive pressure ventilation (iNPPV) and protocol-driven noninvasive positive pressure ventilation (pNPPV), and one examining the role of the physiotherapist in NIV management. Two Level VII expert opinion articles were included supporting the need for NIV protocols and training of staff in appropriate use.

Synthesis

NIV is shown to be associated with a decreased rate of ETI, protecting patients from the trauma involved in this invasive therapy (Digby, 2015; Liu, Zhao, & Tang, 2016; Osadnik et al., 2017; Ouellette et al., 2017; Scala & Pisana, 2018). NIV is supported for use in ARF in the presence of chronic illnesses such as COPD and CPE (Burns, Meade, Premji & Adhikari, 2013; Keenan et al., 2011; Stefan et al., 2018; Vargas et al., 2017). Berg and Donnino (2012) support the use of NIV for pneumonia associated ARF, while Lim et al. (2012) found controversial data for use of NIV in asthmatic clients. Bersten (2011) and Equinas et al. (2014) support the need for protocols and staff training in the use of NIV. Kikichi et al. (2011) investigated outcomes between individual physician-directed noninvasive positive pressure ventilation (iNPPV) and

protocol-based NPPV (pNPPV), finding pNPPV to reduce the time to intubation and to reduce group and hospital mortality.

The remaining studies address specific aspects of NIV therapy that could inform development of an NIV protocol. Alqahtani, Worsley, and Voegeli (2018) found that humidity in NIV increased the development of skin breakdown. BaHammam, Singh, Gupta, Pandi, and Perunal (2018) found full-face and oronasal masks preferable to nasal masks in the acute stage, with weaning to oronasal appropriate after stabilization. Brambilla et al., (2019) suggest a continuous positive airway pressure (CPAP) trial for hypoxic nonhypercapnic ARF, with shift to NPPV if response is poor. Meeder, Tjan, and Zanten (2016) recommend an NPPV prior to ETI as those patients receiving NPPV prior to ETI had better outcomes than those initially intubated without NPPV. Ouellette et al. (2017) recommend spontaneous breathing trials (SBT) for those intubated greater than 24 hours with CPAP, minimal sedation, and NIV post extubation to prevent weaning failure. Ni, Wang, Tu, Liang, and Liang (2017) suggest that NPPV interface intolerance post extubation can be managed with sedation and analgesia.

Four studies are not applicable to the proposed project. Burns, Lelloch, Wisenbaum, Lessard, and Friedrich (2014) discussed the SmartCare automated weaning system that is not available at the facility of study. Simonelli, Paneroni, and Vitacca (2013) discussed the role of the physiotherapist in NIV therapy, and no physiotherapists are available in the facility of study. The two randomized controlled trials described appropriate questions of interest but had not been completed at the time of the search. Therefore no evidence was available to inform the project.

Conceptual Model

The Iowa Model June 2015 Revision: Evidence-Based Practice to Promote Excellence in Health Care, hereafter referred to as the Iowa Model, was applied to the project. The Iowa

Model consists of a triggering issue with a question to be explored. A quality improvement team is then formed to address the question with deliberate consideration of the appropriate disciplines to be included on the team. Collection of historical data within the facility connected with the practice question formed a comparison group for improvement. Research into the body of evidence surrounding the practice question was done as described above to determine best practice. The team designed and implemented a pilot practice change, monitored patient outcomes, and compared them to the historical data previously collected.

The triggering issue for the project was the preliminary gap analysis identifying lack of a noninvasive ventilation (NIV) protocol. The question to be explored was whether an NIV protocol would reduce the number of ETIs, mortality rates, and length of stay (LOS) for all adult ARF patients. The NIV protocol development team (NIV-PDT) included the project leader, respiratory therapy department head, respiratory therapists, the chief hospitalist, the nurse manager of ICU, the nurse informaticist, the Chief Nursing Officer, and the Director of Operations. A literature review was performed as described above informing the development of a protocol by the NIV-PDT. Historical data regarding NIV, ETI, and patient outcomes had been collected by the project leader for comparison against project outcomes. The pilot protocol developed by the team was approved and education of respiratory therapists, nurses, and physicians followed. The protocol was implemented for eight weeks in the ED, ICU, and Medical/Telemetry units. NIV, ETIs, LOS, and mortality rates for adult patients admitted with ARF were collected over the course of the pilot and reported upon conclusion of the pilot. The results were provided to the pulmonary medicine director to inform any modifications desired for a standing protocol. Integration and sustainability of the NIV protocol will be achieved through policy revisions supporting the establishment of an official NIV protocol and policy for the

facility. Dissemination of the results may occur at the corporate level for sister facilities within the corporation. Results will also be presented as the project defense by the project leader and posted in the Liberty University Digital commons.

Summary

The IDSA/ATS guidelines for CAP and the CCCS guidelines for NIV support the development of NIV protocols. Recent research further supports preliminary NIV trials prior to ETI and standardization of care. The IDSA/ATS gap analysis performed by the facility revealed the lack of a NIV protocol. A quality improvement team was formed to address this gap and develop said protocol. Improvement of patient outcomes, specifically decreased number of ETIs, LOS, and mortality rates for adult ARF patients, were monitored and compared to pre-project data.

Section Three: Methodology

Design

The study was an evidence-based practice (EBP) project utilizing a quasi-experimental approach to gather and analyze data. Examination of the effect of NIV protocols on the rate of ETI and mortality and LOS for adult ARF patients was performed. Data gathered was shared during the project and upon completion. Data was also compared to historical data collected before implementation of the protocol.

Measurable Outcomes

The variables of interest include the rate of ETI, average LOS, and mortality rates for adult patients admitted with ARF. The lack of NIV protocols has resulted in a variety of individual physician-directed methods of treatment rather than a standardized approach to care. Development of a protocol was expected to decrease ETIs, LOS, and mortality rates for adult

ARF patients. The protocol was also expected to decrease the incidence of failure to rescue in this patient population.

Setting

The project was implemented in a rural Texas hospital with a 15-bed ED, 12 ICU beds and 36 Medical/Telemetry beds. The organizational culture welcomes EBP initiatives and quality improvement projects. Adults in ARF will first be seen in the ED and determination regarding ventilation and response to treatment evaluated. The NIV protocol would be critical at this juncture of care. NIV could continue in the ICU and Medical/Telemetry units necessitating protocols for these areas as well. NIV is also used as part of the ETI weaning process in the ICU, and established standards could improve the patient experience and outcomes there. Permission to pursue the NIV protocol was granted by the facility and can be found in the appendix.

Population

The population of study included all adult ARF patients treated in the facility during an eight-week period after protocol initiation. Asthma patients were excluded due to lack of evidence of the efficacy of NIV in this population. The hospitalists, along with the respiratory therapists, and nurses in ICU, ED, and Medical/Telemetry were educated regarding the protocol. Documentation indicating protocol implementation, along with ETI, LOS, and mortality for this population were evaluated.

Ethical Considerations

The risk to the patients was reduced through implementation of the protocol, designed to initiate less invasive ventilation prior to ETI. All ARF patients received this evidence-based standard of care, with the historical data serving as the control group. Decreased numbers of

ETIs reduces the complications seen with invasive intubation. The project leader and Chair have completed the CITI training for the protection of human subjects.

Data Collection

Chart reviews were performed to ascertain adherence to the pilot NIV protocol. Patient response to NIV, incidence of ETI, LOS, and mortality rates were also gathered. Data was shared with the NIV-PDT upon project completion. This data was compared to the historical data collected prior to the protocol.

Tools

The major tool for the project is the NIV protocol developed by the NIV-PDT. An audit tool for collection of data for ARF patients, including the ventilation support used, the LOS, and the mortality rate, was used for historical data collection. ARF patient charts were audited with the same tool after initiation of the protocol. An educational presentation was given to the hospitalist group providers, respiratory therapists, and nurses in ED, ICU, and Medical/Telemetry units regarding their roles, and the necessity for and implementation of the protocol. The ED providers group was new to the facility and just adjusting to their new environment and were not included in the education.

Intervention

The lack of NIV protocols results in inconsistent care for adult ARF patients. Education of providers, RTs, and nurses involved in implementation was provided regarding the use of the protocol and the rationale behind the development of the protocol. Implementation of an NIV protocol developed by the NIV-PDT was performed over an eight-week period.

Data Analysis

Historical and post pilot protocol data were analyzed using descriptive statistics to assist in finding trends that support the continued use of the protocol. Implementation of the protocol was expected to decrease the number of ETIs and the associated complications. ARF patient LOS and mortality were also expected to decrease with the protocol.

Section Four: Results

Descriptive Statistics

The measurable outcomes of percentage of ETI, average LOS, and mortality were compared between the historical and pilot groups with the results displayed in Table 1. There was improvement noted in all three measures among the pilot group. The percentage of ARF patients intubated in the historical group was 48.4%, while there were no intubations in the pilot group. The average LOS for the historical group was 5.32 days, and the pilot group average LOS was 4.44 days. There was a 9.7% mortality rate among the historical group, with no mortalities occurring in the pilot group. Of the thirty-six pilot patients, six were placed on hospice for end-of-life care, but there were no deaths during the acute inpatient stay. The results support the use of protocols for respiratory and ventilatory support.

Table 1

Comparison of Measurable Outcomes

Outcome	Historical	Pilot
Percentage of endotracheal intubations	48.4%	0
Average Length of Stay (LOS)	5.32 Days	4.44 Days
Mortality rate	9.7%	0

Protocol adherence and patient response were also monitored during the pilot. Twelve of the thirty-six patients were hypercapnic, and five of those twelve were also acidotic, prompting for initiation of the NIV protocol. BiPAP was initiated immediately for three of the five, with one patient refusing the therapy. The remaining patient did not have an ABG drawn until day four of the stay. On day five, Vapotherm, a warmed, humidified, and pressure regulated high-flow nasal cannula delivery, was initiated, followed by BiPAP. The hospital course continued over seven more days before the patient was transferred to a long-term acute care (LTAC) facility. Table 2 displays the course of these five patients for whom the protocol applied.

Table 2

Protocol Applicable Patient Course

Pt ID	pH	PCO2	Support	Recheck	LOS	Disposition
P-3	7.25	48	2L/NC	5 Hours	12	Transfer to LTAC
P-7	7.22	72	BiPAP	2.5 Hours	4	Discharge with O2
P-11	7.33	57.1	BiPAP	5 Hours	2	Home with Home Health
P-26	7.30	87.5	3L/NC	17 Hours	3	Home on Hospice
P-33	7.29	68.3	BiPAP	2 Hours	3	Home with trilogy for OSA

The additional respiratory support therapy implemented in the pilot group known as Vapotherm was not addressed in the pilot protocol. Two pilot patients received Vapotherm alone, three received alternating Vapotherm and BiPAP, and three received BiPAP alone. Only one of the hypercapnic, acidotic patients received this therapy as described above.

Section Five: Discussion

Implications for Practice

The results of this pilot project support the use of protocols for NIV and other respiratory support therapies. Uniform application of evidence-based practice yields improved patient

outcomes, as well as improved team morale. Consistent delivery of care removes uncertainty among team members regarding implementation and evaluation of care. Protocols for respiratory support allow for more rapid application of these therapies by the respiratory therapists and nurses, thus removing the time element of contacting a provider for orders. Treatment options such as NIV that have been shown to positively impact patient outcomes can be initiated upon initial assessment by respiratory therapists if the patient meets the set criteria. Protocols should indicate time frames for evaluation of the patients and indications for continued therapy or consideration of ETI. The historical group included a patient that was on BiPAP for five days without evaluation of respiratory status via arterial blood gases (ABGs). When this patient arrested, the $PaCO_2$ was 81.7, well above the normal 35–45 range. This could have been avoided if a protocol prompting for periodic evaluation of patients on ventilatory support had been in place. During the interim between the historical study and the pilot project, a patient came into the emergency department with ARF and was placed on BiPAP. When the admitting provider evaluated the patient, the patient was able to answer questions without evidence of respiratory distress, and the BiPAP was discontinued. A few hours later, the patient arrested on the Medical/Telemetry unit. A protocol that called for at least 12 hours of NIV therapy and a reassessment by ABGs prior to discontinuation could have prevented this situation as well.

The use of Vapotherm requires additional study and investigation. There are very few studies regarding the use of this therapy in adults. The recommendations for use are provided from studies performed by the manufacturer rather than an impartial researcher. For the hypercapnic, acidotic patient, this therapy was found to be less effective than BiPAP. The facility could perform their own study of the effectiveness of this therapy and develop guidelines for application of this intervention.

Limitations of the project include the application in a single small facility with sample sizes less than forty patients for both groups. The time frame of the historical data was during the first months of the year when there typically are more cases of respiratory infections; however, the protocol period evidenced a slightly higher number of ARF patients. The small sample size of five ARF patients with both hypercapnia and acidosis limits applicability of results to further studies. The pilot time frame was also limited to two months for data collection, further decreasing the generalizability of the results.

Sustainability

The results of the study and research into appropriate use of the Vapotherm therapy have been shared with the pulmonary medical director. A formal protocol is to be developed by the facility providers including the ED physicians and representatives from the respiratory therapy department. The protocol will provide parameters for initiation of various oxygen/ventilatory support therapies. Institution of such a policy will free respiratory therapists to initiate oxygen/ventilatory support without taking time to obtain an order from the providers. Patients will receive these critical therapies sooner and recovery times will be decreased. The protocol should also address evaluation parameters for patients with ventilatory support, allowing for weaning or adapting therapy according to individual patient response.

Dissemination Plan

The NIV Protocol Project will be submitted to the Liberty University Scholars Crossing. A poster presentation and Podium presentations have also been prepared for sharing these results. The results have been shared with the Director of Quality Management and Regulatory Compliance for report to the corporate superiors. The results may then be shared with sister

facilities within the corporation. Poster and podium presentations have been prepared, as well as a manuscript for potential publication.

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Appendix A: Evidence Table

Article Title, Author	Study Purpose	Sample Characteristics	Methods	Study Results	Level of Evidence	Study Limitations	Supports Practice Change
Alqahtani, J. S., Worsley, P., & Voegeli, D. (2018)	Determine the effect on humidification of CPAP the skin microclimate, barrier function, and risk of pressure ulcer development	Fifteen healthy volunteers	A crossover cohort design. Transepithelial water loss, skin hydration and pH at the bridge of the nose and both cheeks after both non-humidified and humidified CPAP therapy	Humidified NIV was shown to have a higher risk of breakdown and disruption of the interface, while non-humidified therapy resulted in elevated nasal discomfort	Level VI Single descriptive study	Small sample of only 15 healthy adults. Many who require NIV have multiple health challenges	Yes. Withholding humidity could be included in the protocol
BaHammam, A. S., Singh, T. D., Gupta, R., Pandi-Perumal, S. R., (2018)	Investigation of different interfaces for NIV and their effect on treatment success, upper airway patency, mask fitting, and interface related problems	80 studies comparing interfaces during NIV during acute respiratory failure ARF were reviewed and summarized	Systematic review	Oronasal and face masks are preferred for ARF. Fitting to prevent air leaks and skin irritation is needed for successful NIV therapy. Shifting to nasal mask may be done when stabilized, but patient preference must be accounted for. The helmet is a	Level I Systematic review	Multiple studies reviewed comparing multiple NIV interfaces	Yes. Stabilization on Full face or oronasal mask for ARF could be included in the protocol

				promising new interface for NIV.			
Berg, K. M., Donnino, M. W., (2012)	Examination of the evidence supporting NIV, the potential dangers, and guidelines for use	Forty-four studies/articles involving NIV in ARF were analyzed	Systematic review	The use of NIV in hypoxemia related to pneumonia resulted in significantly lower intubation rates, hospital mortality, and complications. Early initiation of NIV is most successful. The strongest evidence for use involves exacerbation of COPD, as many studies have focused on this disease process.	Level I systematic review	Includes the results of many RCTs and also meta-analyses	Yes. NIV use in pneumonia is a significant piece of the protocol
Bersten, A. D., (2011)	Editorial based off Keenan study below	Key points gleaned from guidelines for implementation of NIV	Compilation of key points found in the referred review.	Successful implementation of NIV requires 24-hour availability of experienced team members and monitoring for failure to respond and intubation when indicated.	Level VII Expert opinion of researcher	Support for well-trained team but presented as opinion	Yes. Support for training of staff and providers in management of care
Brambilla, A. M., et al., (2019)	Evaluation of the use of NIV in ARF due to	347 from 19 centers in Italy experiencing	Observational study of the treatment of	CPAP more often used for hypoxemic nonhypercapnic	Level IV Observational study of two	The sample size and multiple center aspects of	Yes. CPAP could be trialed with

	pneumonia outside the ICU, and identification of in-hospital mortality risk factors	ARF associated with pneumonia	pneumonia patients with ARF and use of NIV. CPAP applied to 176 patients and NPPV for 171. Patient blood gas results were monitored, as well as in-hospital mortality	ARF. CPAP failure would often respond to NPPV and prevent the need for intubation. Mortality rates appeared to be associated with the patient's baseline status.	treatment options across 19 facilities	this study increase its validity. The authors concede that the facilities of study are experienced in the use of NIV.	nonhypercapnic patients.
Burns, K. E. A., Meade M. O., Premji A., Adhikari, N. K. J., (2013)	Examination of studies involving weaning from intubation and mechanical ventilation to NPPV versus intermittent positive-pressure ventilation (IPPV) weaning. Reduction of mortality, weaning failure, ventilator-associated pneumonia, ICU and total length of stay, duration of mechanical	Sixteen studies analyzed by four researchers	Systematic review	NPPV significantly reduced mortality and weaning failure. ICU and hospital LOS was also reduced along with duration of mechanical and noninvasive ventilation. Reduced risk of VAP without increased risk of failure to wean or reintubation was also noted.	Level I systematic review	Sixteen RCTS were analyzed with predominantly COPD patients. Effects in other situations requiring ventilation should also be evaluated.	Yes. Supports the use of NPPV as a method to reduce mortality and complications from intubation

	ventilation of support, and adverse events.						
Burns, K. E. A., Lellouch, L., Nisenbaum, R., Lessard, M. R., Friedrich, J. O., (2014)	Comparison of weaning times using automated weaning and spontaneous breathing trials (SBTs) versus non-automated weaning strategies in invasively ventilated critically ill adults. Time to successful intubation, first SBT and first successful SBT, mortality and VAP rates, and the LOS for ICU and hospital were also compared.	10 trials with a total of 654 participants were examined	Systematic review	Automated weaning via the SmartCare system decreased weaning time, time to successful extubation, and LOS in ICU, reducing the percentage of patients requiring mechanical ventilation for 7 or 21 days. These benefits were realized without increased risk of adverse events.	Level I Systematic review	Ten small trials with low to moderate quality of evidence were used to compile data. A larger trial, perhaps in multiple locations would have been preferable.	No. This system is not available in the facility.
Cabrini, L. et al., (2019)	Evaluate early NIV for mild-moderate ARF in non-ICU wards to prevent severe ARF.	520 patients with 260 in each group randomized to receive NIV or treatment as	Tracking of development of severe ARF, 28-day mortality, LOS, the safety of NIV in non-	Trial is ongoing	Level II RCT	The sample size is adequate to inform practice	The results of this study could inform the project but are not yet available.

		usual for mild-moderate ARF	ICU environments				
Digby, G. C., et al., (2015)	Description of NIV practice variation in the acute setting	330 patients treated in 11 Canadian tertiary care centers using NIV for ARF	Collection of data at each facility during a four-week period. Data collected included times locations, indications and initial settings for NIV initiation and discontinuation. Patient characteristics, ABGs upon initiation, goals of care (code status) specialty of ordering provider, and survival status were also recorded.	Wide variability in NIV use among the 11 tertiary care centers studied. This variation could be related to lack of knowledge or familiarity with clinical practice guidelines. COPD and pulmonary edema were the two most common diagnoses for which NIV was initiated and was associated with relativity fewer intubations and lower mortality rates. Patients receiving NIV for ARF secondary to pneumonia had a higher rate of intubation than the previous two diagnoses.	Level VI Single descriptive qualitative study	Descriptive study with multiple variables at play. Provider knowledge, and location within the facility factored into the choice and timing of NIV	Yes. Supports NIV as method to reduce intubation
Esquinas, A. M., et al. correspondence	Correspondence regarding ED	This was not a research article, rather discussion	Discussion between two groups	El-Khatib et al. had investigated the percentage of use	Level VII professional correspondence	Although this article documents the	Yes. This supports the need for

with El-Khatib, M. F., et al., (2014)	protocols and use of NIV	following an investigation into NIV use in Lebanese EDs	interested in the more appropriate use of NIV in the ED environment	of NIV in Lebanese EDs and found only 43% had some form of protocol for the use of NIV. Esquinas et al. called for investigation into the structure, resources and staffing of EDs, as well as guidelines for indication of NIV based on etiology, equipment used, and training of staff in successful application	of expert opinions	correspondence between these groups of providers, valid concerns are raised that should be considered in the development of a NIV protocol.	protocols and adequate training of staff and providers in NIV use.
Keenan, S. P., et al., (2011)	Clinical practice guidelines	An 18-member panel of clinicians reviewed 146 RCTs investigating NIV. The panel was formed by the Canadian Critical Trials group and Canadian Critical Care	Systematic review and compilation of NIV guidelines	NIV was shown to reduce the need for intubation and hospital mortality. Insufficient evidence for support with asthma. Lack of RCTs for CAP with no history of respiratory disease and NIV.	Level I Systematic review and practice guidelines	Global studies investigated. The research supports use of NIV in COPD and cardiogenic pulmonary edema. Use of NIV in patients ARF may be trialed, but insufficient study support for recommendation.	Yes. This supports NIV in two populations, COPD and cardiogenic pulmonary edema. At time of study, lack of evidence for use in asthma or pneumonia

		Society NIV Guidelines		Acknowledge that the possibility of benefit for ARF without COPD may exist, but data had not been collected to support this at the time of the study.			
Kikichi, T. et al., (2011)	Comparison of protocol-based noninvasive positive-pressure ventilation (pNPPV) use in the ED with individual physician directed NPPV (iNPPV)	74 patients with ARF seen in the ED of one facility	pNPPV protocol was developed. Data on 37 patients with ARF treated with iNPPV was collected before protocol implementation, and compared with post implementation application of pNPPV for 37 patients with ARF.	The time to intubation was reduced in the protocol-based NPPV group and hospital mortality was significantly lower. LOS was shorter though not statistically significant.	Level VI Single qualitative study	Single facility study with relatively small sample.	Yes. This supports the creation of a protocol for NIV rather than leaving management up to individual providers without guidelines.
Lim, W. J., et al. (2012)	Determination of the efficacy of NPPV in adults with severe acute asthma in comparison to usual medical	Five studies involving 206 participants were reviewed	Comparison of mortality and tracheal intubation rates, as well as changes in blood gases and LOS	The lack of studies contributes to continued controversy regarding NPPV in asthma patients	Level I systematic review with only five studies found to include in review	Very small sample despite being a review of literature. Contradictory results continue to flame the	Yes. Protocol should exclude asthma for NIV use.

	care with respect to mortality, tracheal intubation, changes in blood gases, and LOS					controversy regarding NPPV for asthma.	
Liu, Y. J., Zhao, J., Tang, H., (2016)	Investigation of the utility of NPPV intervention in patients with ARF	12 studies with a total of 963 patients were examined	Assessment of the effectiveness of NPPV versus conventional mechanical ventilation and/or non-ventilation therapy, mortality rates, and LOS in ICU and hospital	Usage of NPPV was associated with significantly decreased intubation and ICU mortality rates, but did not influence the hospital mortality rate, or ICU or hospital LOS.	Level I meta-analysis of studies	Sample size and characteristics support the validity of the meta-analysis	Yes. Further support for reduction of intubation rates
Luo, Z., et al., (2018)	Comparison of High-intensity versus low-intensity NPPV in acute exacerbation of COPD (AECOPD)	600 patients with AECOPD recruited in 27 respiratory units in university hospitals in China between December 2017 and December 2018	Randomization of eligible participants into high and low intensity groups. Tracking of the need for endotracheal intubation, decrement of CO2 tension 2 hours after therapy, as well as in-house, 28-day and 90-day	Study results not yet available at the time of publishing	Level II Well designed RCT	This seems to be a well-designed study, and the results could inform a NPPV protocol, but those results are not yet available.	No results to inform project

			mortality rates will be documented.				
Meeder, A. M., Tjan, D., H. T., van Zanten, A. R., (2016)	Assessment of rates and predictors of NPPV failure and comparison hospital outcomes of patients with NPPV failure and those intubated without NPPV trial	The records of 40 ARF patients treated with NPPV and 40 primary intubation patients in an ICU in the Netherlands	A retrospective observational study using data from patients with ARF admitted to ICU from 2013-2014. All NPPV patients were evaluated and a sample of primarily intubated patients were selected for comparison of survival rates and risk factors.	Patients with ARF who fail NPPV have worse outcomes than those with successful NPPV. NPPV failure patients do not have improved outcomes over primarily intubated patients. A prospective trial of NPPV is warranted in ARF.	Level IV retrospective observational case-control study	Single center study. Would need replicated studies for increased validity	Yes. NPPV significantly reduces need for intubation and a trial with failed NPPV does not impact outcomes.
Ni, Y. N., Wang, T., Yu, H., Liang, B. M., Liang, Z. A., (2017)	Determine the effect of sedation and/or analgesia as rescue during NPPV in patients with interface intolerance after extubation	80 patients placed on NPPV post extubation with documented interface intolerance were included. Patients studied were admitted to 7 ICUs of one West China	41 of 80 patients received sedation and/or analgesia during the NPPV therapy.	The patients receiving sedation and/or analgesia evidenced a decrease in respiratory failure (15% vs. 38%), and mortality rate (7% vs. 33%), and length of ICU stay after extubation.	Level IV well-designed case-control study. A retrospective study of the effect of analgesia on NPPV tolerance.	Relatively small sample of 80 patients in one facility in China.	Yes. Sedation or analgesia could be included in the NIV protocol for interface intolerance during weaning.

		facility between December 2014 and August 2016.					
Osadnik, C.R., et al. (2017)	Comparison of the efficacy of NIV versus no mechanical ventilation in adults with acute hypercapnic respiratory failure (AHRF) due to AECOPD	1264 patients from 17 clinical trials	Evaluation of mortality rates, intubation rates, and LOS were compared through the studies for AECOPD patients receiving NIV and those who did not.	The risk of death was reduced by 46% and the necessity of intubation was reduced by 65% in NIV patients. NIV patients showed an average 3.4 days shorter LOS than those not receiving NIV.	Level I Systematic review of 17 clinical trials	Though the findings scored as moderate on the GRADE criteria, the number of patients included and the number of facilities studied support the generalizability of the results.	Yes. Support for NIV over withholding of the therapy
Ouellette, D. R., et al. (2017)	Development of practice guidelines and protocols for mechanical ventilation	Multiple studies were included to answer three PICO questions	1st Should SBT be conducted with or without inspiratory pressure augmentation? 2nd does minimizing sedation impact duration of ventilation? 3rd How does NIV compare with no NIV post extubation in duration of	1st For patients ventilated more than 24 hours, initial SBT should be conducted with inspiratory pressure augmentation (CPAP) rather than without. 2nd For patients ventilated more than 24 hours, protocols for minimal sedation should be implemented	Level I Clinical practice guideline post Meta-analysis of available literature	Although this is a joint clinical practice guideline from the American College of Chest Physicians and the American Thoracic Society, each of the three questions was addressed by review of 5-6 clinical trials.	Yes. These are official guidelines to inform the protocol

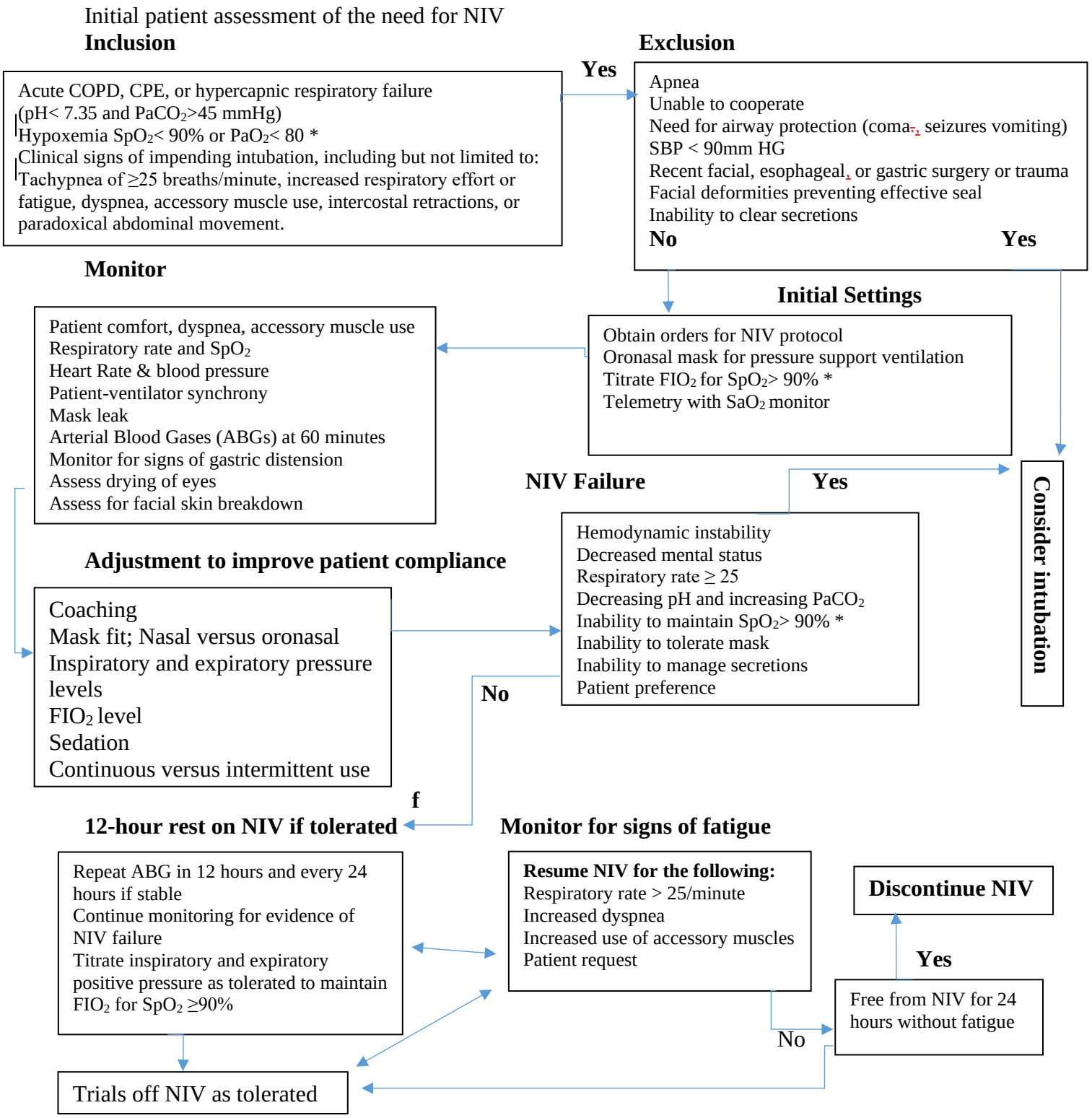
			ventilation, extubation success, duration of ICU stay and short or long-term mortality?	3rd For patients at high risk for extubation failure, preventative NIV is recommended post extubation.			
Scala, R., Pisani, L., (2018)	Update on evidence-based usefulness of NPPV in ARF	116 articles listed in references	A qualitative review and analysis of studies	NPPV can be successful in reducing the intubation rate but should be carried out by skilled teams that can recognize failure and the need for intubation, or discussion with patient and family regarding wishes for DNI status early in treatment.	Level V A qualitative review	No specific recommendations or changes provided for an NIV protocol. Discussion of the need for skilled practitioners to know when and which NIV to use, which interface, and which settings.	No, the effectiveness of NIV is not discussed. The need for skilled practitioners is the focus of the study.
Simonelli, C., Paneroni, M., Vitacca, M., (2013)	Description of implementation of a standardized protocol to NIV adaptation for patients with chronic respiratory disease, and evaluation of the	201 chronic respiratory disease patients were enrolled in cardiopulmonary rehabilitation service (CPRS) over 16 months in one Italian hospital	Measurement of the effectiveness of PT in management of NIV/CPAP	PT may reduce the workload of nurses and physicians in management of NIV/CPAP.	Level VI One qualitative study in one Italian hospital	Evidence from a single study. The role of physiotherapist is more commonly used in rehab setting rather than acute care.	No. The facility does not have a physiotherapist available for this role.

	physiotherapist (PT) role and time-consumption						
Stefan, M., S., et al., (2018)	Comparison of patients hospitalized with pneumonia treated with NIV and invasive mechanical ventilation (IMV)	3971 medical records mined from the Cerner EHR system	A retrospective-cohort study comparing ARF pneumonia patients placed on NIV or IMV or both during their course of treatment	Initial NIV was associated with better survival among the subgroup of patients hospitalized with pneumonia who had COPD or heart failure. Patients who failed NIV had a high in-hospital mortality, emphasizing the importance of careful management of NIV.	Level IV Retrospective cohort study	Very large sample from a wide variety of locations in the United States	Yes. NIV improved survival rate for pneumonia.
Vargas, F., et al., (2017)	Assessment of the efficacy of early NIV in decreasing respiratory failure after extubation in patients with chronic respiratory disorders	144 mechanically ventilated patients with chronic respiratory disorder in six French ICUs between January 2010 and June 2011	Prospective randomized multicenter controlled trials were randomly assigned to receive NIV post extubation or conventional oxygen therapy. 72 patients were assigned to each	Respiratory failure for the NIV group was 8.5% compared to 27.8% for the oxygen group. Reintubation occurred in 8.5% of NIV and 18.1 % of oxygen group. Mortality rates did not differ significantly	Level II A well-designed multicenter RCT	144 patients from six facilities were included in the study. The facilities were all in France and should be supported by replication in other countries.	Yes. NIV is supported as reducing respiratory failure in chronic respiratory disease.

			group. Respiratory failure after extubation, reintubation, ICU mortality and 90-day mortality were tracked for both groups.	between the groups.			

*Note: Melnyk's Level of Evidence (LOE) Pyramid is required for appraising the level of evidence. This appendix is formatted in landscape orientation.

Appendix: B Noninvasive Ventilation (NIV) Pilot Protocol



*Goal O2 saturation may vary in COPD patients. Adjust per provider orders or patient baseline

Appendix C: NIV Audit Tool

NIV Audit Tool

Num	LOS	ARF	O2	NIV	ETI	BiP b4 TI	Hypoxia	Hypercapnia	Disposition

Appendix D: Letter of Permission from Facility of Study

January 11, 2019

Liberty University

ATTENTION: FAITH STERLING

C/O Dr. Kopis

1971 University Blvd.

Lynchburg, VA 24515

Re: Janise Tinsman DNP

To Whom it May Concern:

My name is [redacted] I am the Facility Compliance Officer and Director of Quality Management and Regulatory Compliance for [redacted]. Janise Tinsman is a student enrolled in your DNP program and is slated to begin her course work on January 14, 2019. I, along with [redacted] will serve as her preceptors for the program.

Please accept this written notice permitting Ms. Tinsman to perform duties pursuant to your NonExclusive Student Affiliation Agreement with our facility. On behalf of our facility, [redacted] and I are excited to begin work on reducing mortality and improving the overall care of the pneumonia patient population.

Ms. Tinsman will be performing medical record reviews for data collection, working with a team to implement protocols and order sets, and will be leading a collaborative for a successful implementation of these new protocols.

If you have any further needs, please do not hesitate to contact myself or [redacted] at the contact information below.

Sincerely,

Appendix E: Permission to Use Iowa Model

Permission to Use The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

K

Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>

Reply all

Sun 1/27, 6:32 PM

Tinsman, Janise
Inbox

Action Items

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care.* Click the link below to open.

Citation: Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14(3), 175-182. doi:10.1111/wvn.12223*

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Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

Appendix F:.CITI Training Certificate

CITI PROGRAM

Completion Date 01-Oct-2017
Expiration Date 30-Sep-2020
Record ID 24784235

This is to certify that:

Janise Tinsman

Has completed the following CITI Program course:

Biomedical Research - Basic/Refresher (Curriculum Group)
Biomedical & Health Science Researchers (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Liberty University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w7a9a2b99-cee6-4905-9f9f-1ea258182adc-24784235

Appendix G: Historical Results

Historical O2 Support

Num	LOS	ARF	O2	NIV	ETI	BiP b4 TI	Hypoxia	Hypercapnia	Disposition
1-H	5	Y		N	Y	N	Y	N-35.2	Tx to Dallas
2-H	0	Y	AP	N	N		Y	Y-47.4	DC Home
3-H	6	y	AP	N	N		Y	N-37.36	Return to NH
4-H	2	Y	AP	N	N		Y	Y-45.62	DC Home
5-H	5	Y	AP	N	N		N	N-35.45	DC Home
6-H	7	Y	AP	BiPAP			Y	Y-55.6	Return to NH with BiPap
7-H	13	Y	AP	BiPAP	Y	Y	Y	Y-95.2	Return to NH with BiPap
8-H	3	Y	AP				Y	N-33.4	Return to NH
9-H	0	Y			Y-ED	N	N	N-25.6	Unsuccessful code(met. Acidosis)
10-H	2	Y			Y-ED	N		Y-81	Return to NH
11-H	1	Y			Y-ED	N	Y	Y-58.5	Tx to Baylor FW Multiorgan failure
12-H	7	Y	AP	BiPAP	Y day5	Y	Y	Y-81.7:3/20	VM ED NO REPEAT ABG TILL CODE(UNSUCCESSFUL)
13-H	6	Y			Y-ED	N	Y	Y-54	ASTHMA DC Home
14-H	2	Y			Y-ED	N	N	N-38.1	Hyponatremia Tx to Austin
15-H	7	Y			Y-ED	Refused	Y	Y>100	Returned to NH with BiPap
16-H	7	Y	AP	BiPAP	Y-EMS	N	Y	Y>100	Admit to NH
17-H	6	Y			Y-ED		Y	N- 44.4	extub. And allowed to pass per family request
18-H	3	Y			Y-ED		Y	Y-63.6	Transfer to LTAC
19-H	4	Y	AP	BiPAP	Y-ICU	Y	Y	Y-59.1-64.8	LTAC Round Rock
20-H	9	Y	AP	BiPAP	Y-ED	N	Y	Y>100	admit to NH with BiPap (on Bipap prior to hospital)
21-H	20	Y	AP	BiPAP	Y-ED	Y	Y	Y-90.2	Code 1/8 DC Home
22-H	2	Y	AP				Y	N-42.5	Home with HH
23-H	3	Y	AP				Y	N-37.8	DC Home
24-H	4	Y	AP	BiPAP			Y	Y- 58.5	DC Home
25-H	8	Y	AP				Y	Y(DOC)40.7	DC NH
26-H	11	Y	AP				Y	N-42.6	Returned to NH
27-H	7	Y	AP				Y	N-36.1	DC Home
28-H	10	Y	AP				Y	Y-55.5	DC NH
29-H	3	Y		BiPAP			Y	Y-46.2	DC Home WITH O2. TO GET BiPAP FROM VA
30-H	5	Y	AP				Y	NO ABGS	Return to NH
31-H	4	Y	AP	BiPAP			Y	Y-47.3	DC Home WITH O2

Appendix H: Protocol Results

O2 Support Post NIV Protocol

Num	LOS	ARF	O2	NIV	ETI	BiP b4 TI	Hypoxia	Hypercapnia	Disposition
P-1	7	Y	AP/VT	BiPAP			Y	N	transferrred to Abilene
P-2	2	y	AP	N			Y	N	NH with Hospice
P-3	12	Y	BiPAP/VT	BiPAP			Y	Y	ICU_Tranfered to Abilene LTAC
P-4	8	Y	AP				Y		Pulm.Edema. Hypoxia resolved early with diuresis DC Home
P-5	5	Y	AP				Y	N	Severe sepsis family opted for hospice
P-6	4	Y	BiPAP	BiPAP			Y	Y	BiPAP-NC TRIALS WITH DROP IN Ph&increased PCO2
P-7	5	Y	AP/VT	BiPAP			Y		Bronchitis Home with O2
P-8	7	y	100% NRB	VT			Y	N	Transferred to Pulmonologist in Abilene
P-9	2	Y	AP				Y	N	TELE dc Home with HH andO2
P-10	14	Y	VapoTher				Y	N	Inpt Hospice after cellebellar CVA
P-11	2	y	BiPAP	BiPAP			Y	Y	DC Home with HH
P-12	4	Y	AP				Y	N	DC Home
P-13	2	Y	AP				Y	N	DC with Home O2
P-14	6	Y	AP				Y	Y	Dcd Home
P-15	6	Y	AP				Y		Transferred to inpt hospice
P-16	9	Y	AP				Y		Afib with RVR and osteomyelitis delayed DC home
P-17	3	Y	AP				Y	Y	Dc Home
P-18	3	Y	AP				Y		trasfer to NH
P-19	4	Y	AP				Y	N	Dc Home
P-20	1	Y	31%vm				Y	Y	DC home
P-21	2	Y	3L/nc				Y		Discharged
P-22	2	Y	AP				Y	Y	dC home
P-23	2	Y	AP				Y	Y	Home with HH and Home O2
P-24	2	Y	AP				Y	N	DC AMA
P-25	4	Y	AP				Y	N	DC Home
P-26	3	Y	AP	BiPAP IN ED			Y	Y	Rfeused BiPAP home on hospice
P-27	6	Y	AP				Y	N	DC Home
P-28	5	Y	AP				Y	N	DC Home
P-29	4	Y	AP						CHFexac. DC Home
P-30	2	Y	AP				Y		bilat PE home with hospice
P-31	2	Y	AP				Y		DC Home
P-32	3	Y	AP				Y		DC Home
P-33	6	Y	BiPAP	BiPAP			Y	Y	DC Home with HH

O2 Support Post NIV Protocol

Num	LOS	ARF	O2	NIV	ETI	BiP b4 TI	Hypoxia	Hypercapnia	Disposition
P-34	3	Y	AP				Y		DC Home
P-35	3	Y							DC to NH
P-36	5	Y	AP				Y	Y	DC Home